OCT 2 3 2000

K002589

510(K) SUMMARY

Submitted by:

Michael E. Pfleger
Director, Regulatory Affairs
Alcon Research, Ltd.
6201 South Freeway
Fort Worth, Texas 76134-2099
(817) 551-4877 (Phone)
(817) 551-4630 (Fax)

Device Name:

Common Name: Contact Lens Care Multi-Purpose Disinfecting Solution

Proprietary Name: OPTI-FREE® *EXPRESS*® Multi-Purpose Disinfecting Solution

Indications for Use:

For use in the daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution can also be used as a diluent for OPTI-FREE® SUPRACLENS® Daily Protein Remover or OPTI-ZYME® Enzymatic Cleaner.

Description:

OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution is a sterile, buffered, isotonic, aqueous solution containing sodium citrate, sodium chloride, boric acid, sorbitol, AMP-95, TETRONIC® 1304, with edetate disodium 0.05%, POLYQUAD® (polyquaternium-1) 0.001% and ALDOX™ (myristamidopropyl dimethylamine) 0.0005% as preservatives.

Substantial Equivalence:

OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution is substantially equivalent, in terms of its actions and indications for use, to OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution. cleared for marketing under 510(k) K973332, originally submitted as P830034/S32, K974624 and K983780. OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution meets the guidelines set forth in FDA's May 1, 1997 Guidance for Industry - Premarket Notification 510(k) Guidance Document for Contact Lens Care Products.

Safety and Effectiveness:

Cleaning Studies

Previous studies have demonstrated the cleaning capacity of the revised directions for use (no-rub) (K001214) for OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution. A 90-day clinical study demonstrated the ability of the revised directions for use (no-rub) to keep lenses clean and clinically acceptable for long term use. This clinical study demonstrates the superiority of OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution, used with and without OPTI-FREE SUPRACLENS® Daily Protein Remover versus Bausch & Lomb ReNu Multi-Plus® Multi-Purpose Solution (control) using the manufacturers directions for use (digital rub).

Microbiology Studies

A series studies were completed to demonstrate the microbiological efficacy of OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution. These studies were previously submitted under 510(k) K973332, originally submitted as P830034/S32, K974624 and K983780. These studies demonstrate that OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution meets the stand-alone criteria of the disinfection efficacy test of the FDA May 1, 1997 Guidance for Industry; Premarket Notification 510(k) Guidance Document for Contact Lens Care Products. Additional microbiological studies submitted under 510(k) K001214, were conducted demonstrating the efficacy of OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution under the revised directions for use.

Clinical Study

A 90-day, randomized concurrently controlled, observer-masked (investigator and chemical analyst) and patient-masked, parallel group, multi-site study was conducted to demonstrate the safety and efficacy of OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution. OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution was used with and without OPTI-FREE SUPRACLENS® Daily Protein Remover using the modified directions for use (no-rub). The control used in the study was Bausch & Lomb ReNu Multi-Plus® Multi-Purpose Solution used according to its approved label. All three regimens provided clinically acceptable lens cleanliness when used according to their directions for use as measured by residual lysozyme / protein (HPLC/Florescence) and Rudko observation on Day 90 lenses. As was previously demonstrated in a 30 day lens wear clinical trial (K001214), significantly less residual lysozyme was found on Group IV lenses from subjects in the OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution and OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution / OPTI-FREE SUPRACLENS® Daily Protein Remover regimens compared to lenses from subjects in the ReNu Multi-Plus® Multi-Purpose Solution group.

The safety of OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution used with and without OPTI-FREE SUPRACLENS® Daily Protein Remover, according to the modified directions for use (no-rub), is clinically acceptable and similar to the Bausch & Lomb ReNu Multi-Plus® Multi-Purpose Solution used according to its approved label which requires a digital cleaning rub step.

Biocompatibility Testing

OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution meets the guidelines set forth in the Premarket Notification 510(k) Guidance Document for Contact Lens Care Products.

OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution remains unchanged from the previously approved product except for the labeling. The labeling changes require no new biocompatibility testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 3 2000

Michael E. Pfleger
Director
Regulatory Affairs
Alcon Research, LTD.
6201 South Freeway
Fort Worth, TX 76134-2099

Re: K002589
Trade Name: OPTI-FREE EXPRESS® Multi-Purpose Disinfecting Solution
Modified directions for use (no-rub)
Regulatory Class: II
Product Code: 86 LPN
Dated: August 18, 2000
Received: August 21, 2000

Dear Mr. Pfleger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K002589

Device Name: OPTI-FREE® *EXPRESS*® Multi-Purpose Disinfecting Solution

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Gene Haldenwald

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002589

Prescription Use_____ OR Over-The Counter Use_X_
(Per 21 CFR 801.109)